

juncture, the data may be stored or transmitted/telemetered immediately. The time of transmission is completely dependent on whether the programmer is or is not connected to phone link 56 or satellite link 55 at the time of implant. Assuming that one of these connections is made at some time during the day, the data from Internet interface 53 is uplinked to the Internet via phone line modem connection 56 or telemetric satellite link 55 using data encryption technology for a secure transmission as substantially described in filed application No. 09/431,881, *Method and Apparatus to Secure Data Transfer from Medical Device Systems*, filed November 2, 1999, by Nichols and incorporated herein by reference. Upon reaching Information Network 63, these data are incorporated into the data file containing the complete information relating to the implanting institution, for billing purposes and other uses. These same data are also forwarded to that portion of the network computer related to new build orders for manufacturing, which relates to FIG. 4.

Turning our attention now to FIG. 4, we see the various steps used during the manufacturing process to ensure that the recently implanted ICD (using the example mentioned above) is replaced as quickly as possible. Once the fact that an implant has taken place at a particular institution has occurred and is available in the Information Network 63 (see FIG. 3), that same network, which is constantly monitoring whether a device is to be built as a replacement 70. If not, then the system returns to its monitoring function 72. If such a replacement is required, then the order to build is downloaded to the manufacturing database 74. At the same time, the database enquires whether there are any common requirements needed to manufacture the product 74. If so, then the database will download all pertinent software relative to the implanted device to the automated manufacturing line. Meanwhile, the database is examined to determine if there are any custom specifications required for this replacement 98. If so, the database retrieves any custom software 100, which will then be downloaded into the device's firmware (ROM) during the building of the device 84. The standard data set will include the device type, model number, serial number, name of the implanting physician, the name of the sales representative, and the name of the implanting institution. The customized data set might include (though not limited to), for example, the following: specific functions and/or features, a patient warning alarm, a

voice alert in the patient's own language, customized shipping parameters, shipping labels, patient's name and identification number, name of the implanting institution and physician, scheduled date of implant and/or the location where that implant is to take place (e.g., Operating Room No. 3), as well as the institution's inventory management system label. All these data, when received, will automatically initiate a "build-to-order" replenishment to match and replace the customized device(s) implanted at that institution.

At page 20, line 1, replace the Abstract with the following:

ABSTRACT OF THE INVENTION

A medical device production and supply information management system for just-in-time inventory control at the manufacturing facility, vendor stocks, material/product tracking, distribution and shipping management, to thereby reduce inventory at all points in the product manufacturing distribution/delivery chain. The system is implemented using a preferably Web-enabled information network and data communication with a programmer. The programmer provides access to product information, specification and related data for implanted medical devices from which build-to-order or build-to-replenish commands are issued to the manufacturing center. The system is interactive within the information management system that is integrally and seamlessly connected with patients, hospitals, sales offices and related consumption hubs, including manufacturing facilities.

REMARKS

A. Rejections Under §103

Claims 1-7 were rejected as being obvious from Duffin (U.S. Patent No. 5,752,976) in view of Colligan (U.S. Patent No. 6,298,443). The examiner relies upon Duffin as disclosing a bi-directional communication system between a programmer for an implantable medical device and a remote expert data center. The examiner admits that Duffin does not disclose build-to-order information downloadable to a